

FY 2020-2021 Agency Priority Goal Action Plan

Reduce Per- and Polyfluoroalkyl Substances (PFAS) Risks to the Public

Goal Leader:

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Deputy Goal Leaders:

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Overview

Goal Statement

o **Reduce Per- and Polyfluoroalkyl Substances (PFAS) Risks to the Public.** By September 30, 2021, EPA will meet several of the designated Priority Action milestones in the EPA PFAS Action Plan to establish a framework to understand and address PFAS.

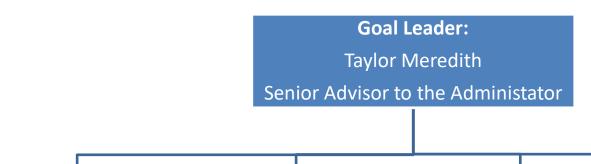
Challenge

- PFAS are a large group of synthetic chemicals used in consumer products and industrial processes. In use since the 1940s,
 PFAS are resistant to heat, oils, stains, grease, and water—properties which contribute to their persistence in the environment.
- Uncertainty of the extent of contamination from PFAS, toxicological information about PFAS, and future regulatory regimes for PFAS are a continuing concern for the federal government, states, tribes, and local communities.
- While EPA has some health and occurrence data for perfluorooctanoic acid (PFOA) and perfluorooctane Sulfonate (PFOS), EPA lacks verified health and occurrence data, as well as validated analytical methods for thousands of PFAS. These data gaps must be overcome to support decision making in the regulatory process. Additionally, research of varying quality on PFAS is being generated by non-USG entities at a relatively rapid rate. EPA assesses new scientific data as it is generated and, if appropriate, amends its research plans accordingly. Work schedules can shorten or lengthen depending upon novel data.
- Additionally, EPA regulatory determinations and toxicity assessments are subject to public comment and federal interagency review. Toxicity assessments are also subject to independent peer review. The Agency reviews and addresses comments before finalizing regulatory and toxicity assessments. Reviewing and addressing unanticipated, substantive comments can result in delays.

Opportunity

- EPA is committed to reduce PFAS risks to the public through implementation of the Agency's <u>February 2019 PFAS Action Plan</u> and through active engagement and partnership with other federal agencies, states, tribes, industry groups, associations, local communities, and the public. EPA's PFAS Action Plan is EPA's first multi-media, multi-program, national research, management and risk communication plan to address a challenge like PFAS.
- EPA will work with partners to accomplish the Agency's goals through pollution prevention, characterization and remediation of contamination in the environment, evaluation of human health and ecological risks, reducing exposures, development of treatment and remediation technologies, dissemination of risk communication materials, and use of enforcement authorities and regulatory approaches as appropriate.

Leadership & Implementation Team



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Goal Structure and Strategies

Strategy 1 – Propose National Drinking Water Regulatory Determination for PFOA and PFOS: Move forward with the drinking water standard setting process outlined in the Safe Drinking Water Act (SDWA) for perfluorooctanoic acid (PFOA) and perfluorooctane Sulfonate (PFOS). The next step in the process involves determining: (1) whether a contaminant may have adverse health effects; (2) whether a contaminant is found in public water systems with a frequency and at levels of concern; and (3) whether, in the sole judgment of the Administrator, there is a meaningful opportunity for health risk reduction through a national drinking water regulation.

Strategy 2 – Finalize interim cleanup recommendations to address groundwater contaminated with PFOA and PFOS: EPA has finalized Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS to support site-specific cleanup efforts. The guidance provides interim recommendations at sites being evaluated and remediated under the EPA Superfund and Resource Conservation and Recovery Act (RCRA) corrective action programs, and may also be useful for other federal agencies, states, and tribes.

Strategy 3 – Finalize toxicity assessments for GenX chemicals and PFBS; and develop draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA:

- O Produce a new toxicity assessment for GenX chemicals and an updated toxicity assessment for perfluorobutane sulfonic acid (PFBS) to facilitate hazard characterization and future risk management decisions. This is needed because industry has phased out the use of PFOS and PFOA in favor of shorter-chain PFAS such as GenX chemicals and PFBS. Toxicity values for these replacement chemicals will help inform risk management decisions of federal agencies, states, and tribes to protect human health.
- Continue to use public peer-reviewed available toxicity information to work towards the development of additional PFAS toxicity assessments for perfluorobutanoic acid (PFBA), perfluorohexanoic acid (PFHxA), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), and perfluorodecanoic acid (PFDA) through the Agency's Integrated Risk Information System (IRIS) program.

Goal Structure and Strategies (continued)

Strategy 4 – Review new PFAS chemicals under premanufacture notice (PMN) and finalize the Long-Chain Perfluoroalkyl Carboxylate (LCPFAC) Significant New Use Rule (SNUR) for existing chemicals:

- O Continue to review all new chemical substances under the Toxic Substances Control Act (TSCA) before they can be allowed to commercialize. EPA has already designated significant new uses for more than 400 PFAS, including for certain PFAS that have been through the new chemical review process but have not yet been commercialized. Anyone who plans to manufacture or import a new PFAS for a use designated as a significant new use must first provide EPA with notice, known as a PMN for new chemicals, or a Significant New Use Notice for a chemical subject to a SNUR. EPA is required under TSCA to review PMNs in a 90-day period with the goal of identifying whether there are unreasonable risks and applying appropriate controls to mitigate risks where identified.
- o Issue a supplemental proposal to the 2015 SNUR on PFAS chemicals in the second quarter of FY 2020 and work toward the target to finalize this SNUR by June 2020, as required by the National Defense Authorization Act for FY 2020. In 2015, EPA proposed the SNUR to complement the long-chain PFAS-phaseout under the 2010/2015 PFOA Stewardship Program. The proposed SNUR, if finalized, will require manufacturers and processors of these chemicals and perfluoroalkyl sulfonate to notify EPA before starting or resuming new uses of these chemicals in any products. EPA must review and make an affirmative determination on the notice before that new use can commence, if at all.

EPA achieved both of the planned milestones in FY 2020 Q1.

Milestones by strategy		FY 2020 Q1	FY 2020 Q2	FY 2020 Q3	FY 2020 Q4	FY 2021 Q1	FY 2021 Q2	FY 2021 Q3	FY 2021 Q4	Pref Dir	Trend	Total
Strategy 1 – Propose National Drinking Water	Target	1	1	-	-	-	1	-	-	↑		3
Regulatory Determination for PFOA and PFOS	Actual	1										1
Strategy 2 – Finalize interim cleanup	Target	1	-	-	-	-	-	-	-	1	7	1
recommendations to address groundwater contaminated with PFOA and PFOS	Actual	1										1
Strategy 3 – Finalize toxicity assessments for	Target	-	-	-	1	2	2	2	1	1		8
GenX chemicals and PFBS & develop draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA	Actual											-
Strategy 4 – Finalize LCPFAC SNUR for existing	Target	-	1	1	-	-		-	-	↑		2
chemicals	Actual											-
Tatal	Target	2	2	1	1	2	3	2	1	1		14
Total	Actual	2										2

Accomplishments:

- EPA transmitted the proposed National Drinking Water Regulatory Determination for Contaminant Candidate List 4 (CCL4) Federal Register Notice, with preliminary determinations for PFOA and PFOS, to OMB on December 3, 2019. This action follows through on EPA's commitment in the PFAS Action Plan to evaluate PFOA and PFOS for potential regulation under the law. EPA publishes preliminary regulatory determinations for public comment and considers those comments prior to making final regulatory determinations. If EPA makes a positive regulatory determination for any contaminant, it will begin the process to establish a national primary drinking water regulation for that contaminant.
- EPA finalized Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS under federal cleanup programs on December 20, 2019. These recommendations provide clear and consistent guidance for federal cleanup sites being evaluated and addressed under Superfund and other federal cleanup programs.

Challenges:

o Nothing identified during the Q1 performance review.

EPA achieved both planned milestones in FY 2020 Q2.

Milestones by strategy		FY 2020 Q1	FY 2020 Q2	FY 2020 Q3	FY 2020 Q4	FY 2021 Q1	FY 2021 Q2	FY 2021 Q3	FY 2021 Q4	Pref Dir	Trend	Total
Strategy 1 – Propose National Drinking Water	Target	1	1	-	-	-	1	-	-	↑	1	3
Regulatory Determination for PFOA and PFOS	Actual	1	1							l		2
Strategy 2 – Finalize interim cleanup	Target	1	-	-	-	-	-	-	-	↑		1
recommendations to address groundwater contaminated with PFOA and PFOS	Actual	1								l		1
Strategy 3 – Finalize toxicity assessments for	Target	-	-	-	1	2	2	2	1	↑		8
GenX chemicals and PFBS & develop draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA	Actual									l		-
Strategy 4 –Finalize LCPFAC SNUR for existing	Target	-	1	1	-	-		-	-	↑		2
chemicals	Actual		1							l		1
Total	Target	2	2	1	1	2	3	2	1	↑		14
Total	Actual	2	2							l		4

Accomplishments:

- EPA proposed the preliminary National Drinking Water Regulatory Determination for Contaminant Candidate List 4 (CCL4) Federal Register Notice, with preliminary determinations to regulate PFOA and PFOS, on February 20, 2020. This notice was published in the Federal Register on March 11, 2020. This action follows through on EPA's commitment in the PFAS Action Plan to evaluate PFOA and PFOS for potential regulation under the law. EPA publishes preliminary regulatory determinations for public comment and considers those comments prior to making final regulatory determinations. If EPA makes a positive final regulatory determination for any contaminant, it will begin the process to establish a national primary drinking water regulation for that contaminant.
- EPA has completed final independent external peer review for the draft PFBS toxicity assessment, following public comment, with a goal of finalizing the assessment in FY 2020 Q3.
- EPA proposed the supplemental LCPFAC SNUR on February 20, 2020, to amend the 2015 proposal to comply with changes made to TSCA in 2016. The SNUR ensures EPA is notified before anyone begins or resumes the import of articles containing long-chain PFAS chemical substances. As part of the Agency's review, EPA has the authority to place restrictions on the import of products containing these chemicals.

Summary of Progress – FY 2020 Q2 (continued)

Challenges:

- The estimated completion date for the final GenX chemicals toxicity assessment was delayed from FY 2020 Q4 to FY 2021 Q1 to reflect additional time needed to evaluate new toxicity literature, consider an analysis from the National Institute of Environmental Health Sciences (NIEHS)/National Toxicology Program (NTP) Pathology Working Group, and conduct and respond to additional external peer review.
- EPA anticipates finalizing the LCPFAC SNUR in FY 2020 Q3; however, this expedited timeframe depends on accelerated internal and interagency review.

EPA achieved the planned milestones in FY 2020 Q3.

Milestones by strategy		FY 2020 Q1	FY 2020 Q2	FY 2020 Q3	FY 2020 Q4	FY 2021 Q1	FY 2021 Q2	FY 2021 Q3	FY 2021 Q4	Pref Dir	Trend	Total
Strategy 1 – Propose National Drinking Water	Target	1	1	-	-	-	1	-	ı	↑	\	3
Regulatory Determination for PFOA and PFOS	Actual	1	1							_		2
Strategy 2 – Finalize interim cleanup	Target	1	-	-	-	-	-	-	-	↑	=	1
recommendations to address groundwater contaminated with PFOA and PFOS	Actual	1								ı		1
Strategy 3 – Finalize toxicity assessments for	Target	-	-	-	1	2	2	2	1	↑		8
GenX chemicals and PFBS & develop draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA	Actual									l		-
Strategy 4 –Finalize LCPFAC SNUR for existing	Target	-	1	1	-	-		-	-	↑		2
chemicals	Actual		1	1						ı	/ I	2
Tatal	Target	2	2	1	1	2	3	2	1	1		14
Total	Actual	2	2	1								5

Accomplishments:

- EPA finalized the LCPFAC SNUR as planned on June 22, 2020. This final rule strengthens the regulation of PFAS by requiring notice and EPA review before the use of long-chain PFAS that have been phased out in the United States could begin again. Additionally, products containing certain long-chain PFAS used in a surface coating and carpets containing perfluoroalkyl sulfonate chemical substances can no longer be imported into the United States without EPA review.
- On June 10, 2020, EPA closed the docket soliciting public comment for EPA's Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List (CCL4). EPA proposed the CCL4, including preliminary determinations to regulate PFOA and PFOS, on February 20, 2020. This notice was published in the Federal Register on March 11, 2020. This action follows through on EPA's commitment in the PFAS Action Plan to evaluate PFOA and PFOS for potential regulation under the law. EPA is considering comments received in the public docket prior to making final regulatory determinations. If EPA makes a positive final regulatory determination for any contaminant, it will begin the process to establish a national primary drinking water regulation for that contaminant.
- o On May 29, 2020, EPA initiated interagency review on the final draft PFBS toxicity assessment. The assessment will be finalized after review in FY 2020 Q4.

Challenges:

o Finalizing the PFBS toxicity assessment in FY 2020 Q4 depends on comments received from interagency review

EPA missed the planned milestone in FY 2020 Q4 (final toxicity assessment for PFBS).

Milestones by strategy		FY 2020 Q1	FY 2020 Q2	FY 2020 Q3	FY 2020 Q4	FY 2021 Q1	FY 2021 Q2	FY 2021 Q3	FY 2021 Q4	Pref Dir	Trend	Total
Strategy 1 – Propose National Drinking Water	Target	1	1	1	-	-	1	-	-	↑	\	3
Regulatory Determination for PFOA and PFOS	Actual	1	1	-	-					l		2
Strategy 2 – Finalize interim cleanup	Target	1	-	-	-	-	-	-	-	↑		1
recommendations to address groundwater contaminated with PFOA and PFOS	Actual	1	-	-	-					l		1
Strategy 3 – Finalize toxicity assessments for	Target	-	-	-	1	2	2	2	1	↑		8
GenX chemicals and PFBS & develop draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA	Actual	-	-	-	0					l		-
Strategy 4 –Finalize LCPFAC SNUR for existing	Target	-	1	1	-	-	-	-	-	↑		2
chemicals	Actual	-	1	1	-					l		2
Tatal	Target	2	2	1	1	2	3	2	1	↑		14
Total	Actual	2	2	1	0					l		5

Accomplishments:

- EPA is reviewing public comments on the proposed fourth regulatory determination and preparing the materials for the final regulatory determination for PFOA and PFOS in drinking water. These materials include the federal register notice and supporting documents. The final regulatory determination is scheduled for transmission to OMB in FY 2021 Q1.
- A draft toxicity assessment for PFBA has been developed and reviewed by the IRIS interagency working group and members of the PFAS
 technical working group.
- o In FY 2020, EPA received 5 new chemical notices for PFAS chemicals (4 PMNs, 1 Significant New Use Notice), all of which are all still under review. EPA also received 12 Low Volume Exemption (LVE) notices (covering chemicals manufactured at 10,000 kg/year or less) for PFAS chemicals; 8 were granted, with specific conditions to address potential for unreasonable risks, 1 was withdrawn, and 3 are still being reviewed.

Challenges:

- EPA did not complete the PFBS toxicity assessment in FY 2020 Q4 as planned, but has resolved all interagency comments and completed interagency review. The PFBS assessment is being finalized.
- EPA does not expect to meet the FY 2021 Q1 completion date for the GenX Toxicity Assessment because EPA is continuing to evaluate and review new information.
- Public release of the draft toxicity assessment for PFBA in FY 2021 Q1 depends in part on the nature of the comments received from interagency reviewers and the work required to address those comments.

Key Milestones

Strategy 1 – Propose National Drinking Water Regulatory Determination for PFOA and PFOS

Key Milestones	Due Date	Status	Change from Last Quarter	Comments
Transmit Federal Register Notice (FRN) on the proposed regulatory determinations for CCL4 contaminants (Regulatory Determination 4) to OMB for Interagency Review. Regulatory Determination 4 will include PFOA and PFOS.	Q1/FY 2020	Complete	No Change	On December 3, 2019, EPA transmitted the FRN to OMB.
Administrator signature on the Proposed Regulatory Determination 4 FRN.	Q2/FY 2020	Complete	No Change	The FRN was published on March 11, 2020.
Prepare final regulatory determination notice for Administrator signature in the Federal Register.	Q2/FY 2021	On Track	No Change	EPA is reviewing comments submitted through the public docket, which closed on June 10, 2020.

Strategy 2 – Finalize interim cleanup recommendations to address groundwater contaminated with PFOA and PFOS

Key Milestones	Due Date	Status	Change from Last Quarter	Comments
Finalize interim recommendations for addressing groundwater contaminated by	Q1/FY 2020	Complete	No Change	EPA issued Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS on December
PFOA and PFOS.		-	_	19, 2019.

Strategy 3 – Finalize draft toxicity assessments for GenX chemicals and PFBS; and additional toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA

Key Milestones	Due Date	Status	Change from Last Quarter	Comments
Publish final Toxicity Assessment for PFBS.	Q4/FY 2020	Delayed	Changed from On Track to Delayed	EPA published a draft toxicity assessment for PFBS in FY 2019. After receiving public comments on the draft, EPA repeated external peer review on the assessment in FY 2020 Q2. The assessment has completed final interagency review and is undergoing final internal briefing, editing and 508 compliance prior to publication.

Key Milestones (continued)

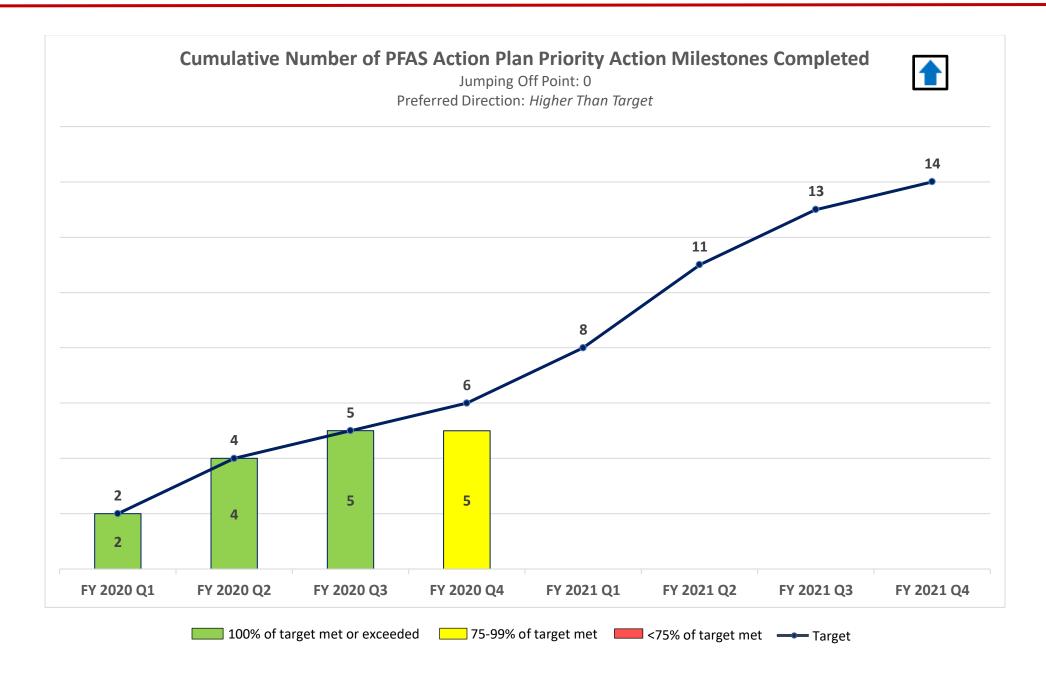
Key Milestones	Due Date	Status	Change from Last Quarter	Comments
Publish final GenX Toxicity Assessment.	Q1/FY 2021	Postponed	Changed from On Track to Postponed	EPA received the analysis on its draft assessment from the Environmental Health Services (NIEHS)/National Toxicology Program (NTP) Pathology Working Group in FY 2020 Q1 and is currently evaluating that analysis. EPA does not expect to meet the end of FY 2021 Q1 completion date for the GenX Toxicity Assessment. EPA is continuing to evaluate and review new information.
Public release of draft toxicity assessments for PFBA and PFHxA for public comment.	Q1/FY 2021	On Track	No Change	These are best estimates on timing. The IRIS PFAS Systematic Review Protocol (which presents the methods for conducting the systematic reviews and dose-response analyses for the draft IRIS PFAS assessments) was released for a 45-day public comment period on November 8, 2019. The first draft PFBA assessment is finished and is currently undergoing interagency review prior to release for public comment.
Submit draft toxicity assessments for PFBA and PFHxA for external peer review.	Q2/FY 2021	On Track	No Change	See above.
Public release of draft toxicity assessments for PFDA and PFHxS for public comment.	Q2/FY 2021	On Track	No Change	These are best estimates on timing. The IRIS PFAS Systematic Review Protocol (which presents the methods for conducting the systematic reviews and dose-response analyses for the draft IRIS PFAS assessments) was released for a 45-day public comment period on November 8, 2019.
Submit draft toxicity assessments for PFDA and PFHxS for external peer review.	Q3/FY 2021	On Track	No Change	See above.
Public release of draft toxicity assessment for PFNA.	Q3/FY 2021	On Track	No Change	These are best estimates on timing. The IRIS PFAS Systematic Review Protocol (which presents the methods for conducting the systematic reviews and dose-response analyses for the draft IRIS PFAS assessments) was released for a 45-day public comment period on November 8, 2019.
Submit Draft toxicity assessment for PFNA for external peer review.	Q4/FY 2021	On Track	No Change	See above.

Key Milestones (continued)

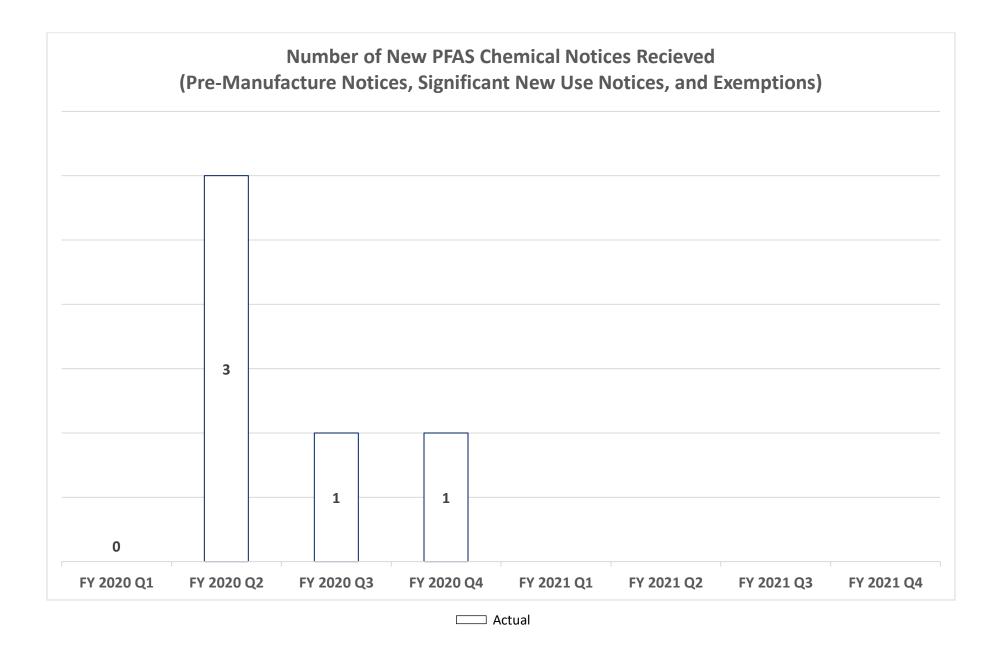
Strategy 4 – Review new PFAS chemicals under PMN and finalize the LCPFAC SNUR for existing chemicals

Key Milestones	Due Date	Status	Change from Last Quarter	Comments
Supplemental proposed SNUR for LCPFAC and perfluoroalkyl sulfonate chemicals	Q2/FY 2020	Complete	No Change	EPA issued the supplemental proposal on February 20, 2020.
Final SNUR for LCPFAC chemicals	Q3/FY 2020	Complete	No Change	EPA finalized the SNUR on June 22, 2020.

Key Indicators



Key Indicators (continued)



Additional Information

Data Accuracy and Reliability

 Data sources for key milestones are Federal Register notices and internal tracking systems. There are no quantitative calculations, significant data limitations or data quality issues.

Contributing Programs

- EPA Office of Water
- o EPA Office of Research and Development
- o EPA Office of Land and Emergency Management
- o EPA Office of Chemical Safety and Pollution Prevention

Other Federal Agencies / Stakeholders / Congressional Consultations

- Agency for Toxic Substances and Disease Registry (HHS)
- Department of Defense